K013798

DEC 1 9 2001

ATTACHMENT 6 - 510(k) Summary

1. **Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 02451
Telephone Number: 781-890-0001
Fax Number: 781-890-6464
Contact Person: Linda Jalbert
Director, Regulatory Affairs

2. **Name of the Device**

Trade Name: Prosthetic Accessories to the ITI® DENTAL IMPLANT SYSTEM
Common Name: Endosseous dental implants
Classification Name: Endosseous dental implants
21 CFR 872.3640

3. **Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

ITI synOcta Abutment (K990342)
ITI Temporary Posts (K990342)
ITI Plastic Copings (K990342)
ITI Healing Cap (K003271)
ITI Closure Screw (K894844)

4. **Description of the Device**

The ITI Dental Implant System is an integrated system of endosseous dental implants which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, abutments, and surgical and prosthetic parts and instruments. The devices covered by this submission include several prosthetic accessories (abutment, titanium temporary posts, plastic burnout copings, and titanium healing caps).

5. **Intended Use of the Device**

The abutment is placed into the dental implant to provide support for a prosthetic restoration such as a crown or bridge. The titanium temporary posts are screwed into the dental implants and serve as a base for a temporary prosthetic restoration. The plastic burn-out copings provide a cast inner surface for mating with the abutment and implant and are for use in casting restorations directly from porcelain- fused-to-metal alloy without the use of machined metal components. The healing cap and closure screw are titanium devices which are mounted onto the dental implant before the soft tissue is sutured in place around the implant and which are intended to protect the inner configuration of the implant. The healing cap also protects the outer 45° shoulder of the implant during the healing phase and helps stabilize and maintain the soft tissue.

6. Basis for Substantial Equivalence

The subject devices are substantially equivalent to previously cleared ITI abutments, temporary posts, burn-out copings, healing caps, and closure screws. The intended uses of the subject devices are identical to the predicate devices.

The subject devices have the same material composition as previously cleared ITI devices. In addition, the designs of the subject devices are similar to, and in some respects identical to, the previously cleared ITI devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2001

Institut Straumann AG
C/O Ms. Linda Jalbert
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K013798
Trade/Device Name: Prosthetic Accessories to the ITI Dental Implant System
Regulation Number: Dental Implant
Regulation Name: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: November 7, 2001
Received: November 15, 2001

Dear Ms. Jalbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Prosthetic Accessories to the ITI® Dental Implant System

Indications For Use:

The abutment is placed into the dental implant to provide support for a prosthetic restoration such as a crown or bridge. The titanium temporary posts are screwed into the dental implants and serve as a base for a temporary prosthetic restoration. The plastic burn-out copings provide a cast inner surface for mating with the abutment and implant and are for use in casting restorations directly from porcelain- fused-to-metal alloy without the use of machined metal components. The healing cap and closure screw are titanium devices which are mounted onto the dental implant before the soft tissue is sutured in place around the implant and which are intended to protect the inner configuration of the implant. The healing cap also protects the outer 45° shoulder of the implant during the healing phase and helps stabilize and maintain the soft tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

A. Blackwell for M.S. Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K013798